Introduction

This report explains the methods by which a foreign company can register its medical devices to be sold in Brazil. Particular attention is given to the registration requirements established by Brazil's Food and Drug Administration (FDA) counterpart, the National Health Surveillance Agency (ANVISA).

The first step is to either open a subsidiary in Brazil or find an importer to officially represent your company in the country. The subsidiary or importer will need to receive authorization from ANVISA to import and work with medical devices.

Your subsidiary or importer must file a request to operate with the local Health Surveillance Secretariat in order to receive authorization to operate. The local agency will visit your operations before granting authorization to operate. This procedure usually takes 3 to 12 months depending on the company's location.

The second step is to register your product in Brasilia, at the National Health Surveillance Agency (ANVISA). Collegial Directory Regulation (RDC185/2001) will guide you through all the procedures for registering medical devices.

Medical Devices comprise the following products:

- Diagnostic equipment, therapy equipment, medical hospital support equipment, disposable materials or devices, implant materials or devices, medical-hospital supports materials and devices, in-vitro diagnostic products.

Product registration is valid for five years, and renewable for five additional years. However, to renew the product, the company will need to go through the registration process again. Before registering the product, ANVISA will classify the product according to its risk level.

The classifications are:

Level I – product with little health risk, but needs registration;
Level II – product with low health risk;
Level III – product with medium health risk;
Level IV – product with high health risk.

In order to guarantee the correct and safe use by the consumer; the Code of Consumer Protection and Defense, approved by Law n. 8.078 on September 11, 1990, imposes on all manufacturers the obligation to provide necessary and appropriate information regarding their products.

The Sanitary Surveillance Secretariat shall grant registration, revalidation, alteration or cancellation of the product after technical analysis of the content of the documents submitted

Procedures for Product Registration:

DOCUMENTS FOR APPLICATION

I. Registration of the Product

In order to register products used in in-vitro diagnosis, the applicant must present the following documents:

1. Application form, filled out in accordance with instructions contained in Manual available at the Sanitary Surveillance Secretariat;

2. Copy of your public payment voucher (DARF-code 6470) at the Bank of Brazil;

3. Copy of the operation permit, issued by the State Health Secretariat;

4. Copy of your company's operation authorization, issued by the Sanitary Surveillance Secretariat of the Ministry of Health;

5. Copy of the technical responsibility certificate, issued by the respective professional entity;

6. Models of the labels used in the packaging of the product, in two copies;

7. Model of the instructions for use and guidelines to the consumer, in two copies;

8. Technical report (a description is provided below);

9. Proof of product registration at the manufacturing country's authorized health agency (in the case of imported products or in the case of no such registration, a copy of the certificate of free trade is necessary);

10. Copy of the legal document, in which the manufacturer of the product authorizes the applicant to represent and to commercialize its product in the Country (together with sworn translation in Portuguese in the case of an imported product).

Registration Revalidation

Registration revalidation must be required at least 6 (six) months prior to the maturity of the registration. The applicant must present the following documents:

1. Application form, filled out in compliance with instructions contained in Manual available at the Sanitary Surveillance Secretariat;

2. Copy of the public payment voucher (DARF-code 6470) at the Bank of Brazil;

3. Proof of industrialization of the product in the first period of validity of the registration;

Complementary Documents

When applicable, the following documents must be attached to the application for registration, revalidation or alteration of the registration:

1. Copy of all the printed material related to the product;

2. Report of prior analysis carried out by unit of the National Network of Public Health Laboratories, as provided for in the technical regulation issued by the Sanitary Surveillance Secretariat;

3. Proof of compliance with the Guide for Good Manufacturing Practices of products used in in-vitro diagnosis, as provided for in the technical regulation issued by the Sanitary Surveillance Secretariat.

4. Term of responsibility, signed by the legally responsible expert in charge;

LABELS

I. Labeling Information

The labeling information provided must contain the following information in Portuguese:

1. Trade name and brand of the product;

2. Name of the applicant;

3. Address and company registration number;

4. Origin of the product with the name and address of the manufacturer;

5. Field of the registration number of the product preceded by the acronym of the competent sanitary surveillance agency of the Ministry of Health;

6. Field of the batch or shipment number;

7. Field of the date of manufacture and period of validity or expiration date of the product;

8. List of the components that constitute the whole of the product, displaying respective amounts;

9. Indication of metric units, such as volume, weight, activity or other characteristic units of each component of the product, in compliance with the international unit system;

10. Inscription "Single Use," if that is the case;

11. Description of the purpose or use of the product;

12. Description of the precautions, special care and clarifications on the risks derived from handling and disposal of the product, including phrases such as "Toxic", " Potentially Infectious" or "Radioactive", among others, with the corresponding international symbol;

13. Name of the technician responsible, with registration number and acronym of the respective professional entity;

14. Indication of adequate storage and transport conditions for the product, including, among others, the limits of temperature, humidity or protection against light, as appropriate.

II. Implementation of Labeling Information

1. All information submitted must be displayed on the label of the external package of the product.

2. The information referred to in items 1, 2, 5, 6, 7, 9, 10, 12 and 14 must be displayed on the label of the internal package of the product.

3. The information referred to in items 11, 12 and 14 may appear on the labels with the phrase "See Instructions for Use ."

INSTRUCTIONS FOR USE

I. Content of the Instructions for Use

Satisfactory product instructions must contain the following information in Portuguese, in the order indicated:

1. Trade name and brand of the product;

2. Description of the purpose or use of the product, in accordance with information on the labels;

3. Description of the principle action or application of the product, describing the scientific foundation as well as a brief explanation of the methodology, techniques or reactions involved;

4. List of all components provided with the product, describing the qualitative and quantitative technical specifications or characteristics of each component, in accordance with the information on the labels;

5. List of all unprovided materials, devices, accessories, inputs or equipment (whether for consumption or not), that are necessary for proper use of product, indicating the form and condition of procurement;

6. Indication of adequate storage and transport conditions to guarantee the stability of product components, including, among others, the limits of temperature, humidity or protection from light (where appropriate), as well as the description of appropriate tests (when applicable), to identify physical, chemical or biological instabilities, with a view toward ensuring adequate product performance.

7. Description of the precautions, special care and clarifications of the risks of product use, in accordance with the label information, detailing, when applicable:

a) Alterations of the characteristics of the product;

b) Precautions and care as to handling of the product;

c) Guidelines for correct and safe disposal of the product;

8. Description of the measurement process, detailing:

a) The preparation of the measurement, with all introductory operations necessary for the correct application of the product, including adequate instructions for reconstitution, mixing, dilution or other form of preparation of the work reagents, as well as mention of the specifications of the dilatants to be used;

b) Application techniques of the reagents and other components of the product, describing the volumes used, the time required for each stage or phase, the physical conditions of the room, as well as the adjustments of the measuring instruments for the product, technique or reaction;

c) Information on relevant additional procedures to carry out measurement, including data on the stability of the final product, technique or reaction and the period of time within which the product can be measured with accuracy;

9. Information on the limitations of the measurement process, including guidance on the use of more specific or sensitive additional tests, when the results thus obtained suggest it;

10. Guidance on internal quality control to be adopted by the user to ensure adequate performance of the measurement process;

11. Description of the performance characteristics of the product, detailing:

a) The inaccuracy with recovery data and comparison with known reference method, or;

b) The imprecision with repeatability and reproducibility;

12. List of the bibliographical references whose content is the basis of or proves the information provided;

13. Indication to the consumer of the quality guarantee terms and conditions of the product;

14. Name of the applicant, company registration number and address;

15. Origin of the product, indicating the name and address of the manufacturer;

16. Indication of customer service, containing all necessary information for the user to contact the supplier;

17. Date of editing of the instructions for use, with the month and year of editing or revision.

TECHNICAL REPORT

I. Content of the Technical Report

The technical report provided must contain the following information:

1.Forms of presentation of the product and the composition of each one of the components that constitute the whole of the product, including the name and synonyms of each substance (active or not), that is present in each unit of the product, as well as the indication of the metric units of volume, weight, activity or other characteristic unit of each component, in accordance with the information on the labels and instructions for use;

2. Description of the purpose or use of the product, in accordance with the information on the labels and the instructions for use;

3. Description of the precautions, special care and clarifications on the risks resulting from handling and disposal of the product, when appropriate, in accordance with the information on the labels and instructions for use;

4. Description of quality control procedures and manufacturer validation of raw materials, components, manufactured materials, intermediate products and finished product, with proof of their execution, or proof of compliance with the requirements of the Guide for Good Manufacturing Practices of products instituted by the Sanitary Surveillance Secretariat;

5. Basic flowchart of the production process containing manufacturing phases or stages, with a brief description of each phase or stage leading to the finished product;

6. Detailing of the comparative studies carried out for determination of sensitivity, specificity, reproducibility, repeatability and stability of the product, in accordance with the information in the instructions for use

II. Presentation of the Technical Report

The technical responsible shall take on responsibility for the information provided by the applicant in the technical report, which must contain the name and signature of the technical expert in charge.